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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	**PAPER NUMBER**
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,348	MBOW ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to methods of generating monoclonal antibodies in Th1-biased rodents, classified in class 530, subclass 388.15 and methods of generating human monoclonal antibodies in C57BL/6 mice, classified in class 800, subclass 6.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) anti-IL-12 antibody

Specie B) anti-IFN-γ antibody

Specie C) anti-IL-8 antibody

Species A-C are distinct and unrelated antibodies each being directed to a distinct and unrelated antigen. Accordingly, each of the antibodies would affect a different arm of the cellular or humoral immune response insofar as modifying the involvement of the respective cytokine in signaling pathways leading to immune cell activation, clonal expansion, increased immune cell survival, antibody production or even cell death. Additionally, it should be noted that antibody binding to some cytokines serves to promote the serum half-life of the cytokine, so the effects of each of the antibodies of Species A-C would be variable. As a result, due to the different and distinct methodologies required for each species, searching all of the species would be an undue search burden on the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 2 are generic as to Species A-C.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A1) pegylated IL-4

Specie B1) pegylated IL-5

Specie C1) pegylated IL-6

Species A1-C1 are distinct and unrelated cytokines. Accordingly, each of the cytokines would effect a different arm of the cellular or humoral immune response insofar as their respective involvement in signaling pathways leading to immune cell activation, clonal expansion, increased immune cell survival, antibody production or even cell death. Accordingly, the effects of each of the cytokines of Species A-C would be variable. As a result, due to the different and distinct methodologies required for each species, searching all of the species would be an undue search burden on the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 2 are generic as to Species A1-C1.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Mr. Kirk Baumeister on December 11, 2005 a provisional election was made without traverse to prosecute the invention of an anti-IL-12 antibody (Th1 antagonist), claim 8 and a pegylated IL-4 (Th2 agonist), claim 9. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 1-15 are all the pending claims and are all the claims under examination with the species of pegylated Il-4 and anti-IL-12 antibody. Claims 8 and 9 are objected to as containing non-elected subject matter.

Information Disclosure Statement

2. The Examiner has considered the U.S. patent reference as well as the non-patent literature references cited in the IDSs submitted on October 16, 2003 and May 19, 2004. Accordingly, the references have been entered and made of record.

Specification

3. The use of the trademarks HuMAb-mouse® and XenoMouse® has been noted in this application on page 3 of the specification. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

4. Claim 2 is objected to because of the following informalities: claim 2 should recite the steps a)-d) whereas the claim now recites steps a), b), d) and d). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 7, 9 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 2 (step d), first occurrence) and Claim 14 (step c)) are indefinite for each reciting the phrase "administering the antigen without a foreign adjuvant". Applicants' specification does not distinguish a foreign adjuvant from a non-foreign adjuvant, and so the meaning of the phrase is unclear. At page 4, lines 24-34, the specification describes an "adjuvant molecule" and sets forth examples thereof. Thus, it is unclear if "foreign adjuvant" refers to an autologous or heterologous adjuvant molecule of the types disclosed in the specification.

b. Claim 7 is indefinite for reciting the phrase "interferes with Th1 development" because it is unclear whether interfering with development refers to preventing or modifying development of Th1 cells from a precursor stage or ablating immature Th1 cells populations to prevent further development.

c. Claim 9 is indefinite for reciting the phrase "wherein the Th2 agonist is modified to extend its half-life" because it is not clear how the Th2 agonist is modified or what modifications are contemplated. Also, it is unclear as to what the half-life is for a Th2 agonist much less a modified Th2 agonist, and the extent to which it is extended by the modification.

7. Claims 2 (step d), first occurrence), 13 and 14 (step c)) recite the limitation "the antigen". There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pegylation of IL-4 in a method of generating monoclonal antibodies, does not reasonably provide enablement for a modified pegylated IL-4 to prolong the half-life. Applicants' claims are enabled for a pegylated IL-4, however, Applicant's claims are not enabled for just any modification, nor that modification would confer an extended half-life to the Th2 agonist. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability of the art, the breadth of the claims, the quantity of experimentation which would be required in order to practice the invention as claimed.

Claim 9 is broadly drawn to modifying pegylated IL-4 in order to extend the half-life of the agonist. Agents used to stabilize the half-life of high molecular weight polypeptides and that are known in the art include pegylation, dextran, poly[Glu-Lys],

pullulan, modified polyaspartate or fatty acids as well as coupling with gamma-globulin (Mikiyama et al., USPN 5,264,209; issue date November 23, 1999; cited in the IDS of October 16, 2003).

The specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Thus Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed modified IL-4 in a manner reasonably correlated with the scope of the claims broadly including just any modified form of IL-4. The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 19, 24 (CCPA 1970).

Example I of the specification describes the preparation of pegylated IL-4 (page 6, lines 19-29) and co-administration of the molecule with anti-IL-12 antibody to mice in order to enhance production of antigen-specific serum IgG. The specification does not teach how to modify just any IL-4 and what other modifications are contemplated, for example, whether the modification is introduced into the chemical core structure of the agonist or chemically complexed to the agonist. The specification is silent as to what the half-life is for just any modified IL-4 much less for a pegylated IL-4 molecule. Thus, the specification does enable IL-4 being conjugated to, for example, dextran, poly[Glu-Lys], pullulan, modified polyaspartate or fatty acids or with gamma-globulin.

Additionally, the specification is also silent as to the extent to which the half-life of IL-4 is extended by any modification much less a pegylated IL-4 molecule which retains its biological activity. Mori et al. (J. Immunol. 164: 5704-5712 (2000); cited in the

specification at page 4, lines 9-10) describe attaching a neutralizing anti-IL-4 antibody to IL-4 in order to extend the in vivo half-life. Pepinsky et al. (J.Pharm. & Exp.Therapeutics 297:1059-1066 (2001) also cited in the specification at page 4, lines 8-9), describe increased systemic exposure of pegylated interferon-β-1a in monkeys, rats and mice. Thus claims directed to extending the half-life of IL-4 are not enabled where there is no support in the specification as originally filed, showing that pegylated IL-4 alone, or when co-administered with an IL-12 antibody under the method conditions, would have a longer serum half-life compared to unconjugated IL-4.

Without such guidance, the modifications which can be made to IL-4 without affecting its biological potency yet extending its serum half-life, are unpredictable and the experimentation left to those skilled in the art is unnecessary and improperly extensive and undue. See Amgen, Inc v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 18 USPQ 1016 (Fed. Cir. 1991) at 18 USPQ 1026, 1027 and Ex Parte Forman, 230 USPQ 546 (BPAI 1986).

Due to the large quantity of experimentation necessary to demonstrate prolonged serum half-life, biological potency and biodelivery of modified pegylated IL-4 under the instant claimed method conditions, the lack of guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, the state of the art establishing limited success with modification methods of high molecular weight proteins, and the breadth of the claim which fails to recite the kind of Th2 agonist, the specification fails to teach the skilled artisan how to make and use the invention.

9. Claims 1, 2, 12, 14 and 15are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for producing monoclonal antibodies by generic rodent strains and human monoclonal antibody production by specific transgenic rodents, does not reasonably provide enablement for expression of a human monoclonal antibody by any generic rodent much less a human monoclonal antibody by a generic mouse. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The Wanda factors are set forth under section 8, *supra*.

Dependent Claim 12 and independent Claims 14 and 15 broadly recite methods for producing a human monoclonal antibody from a generic rodent. Examples of rodents which produce monoclonal antibodies falling within the scope of the claims include but are not limited to those cited in the specification and encompass: rodents in general (p. 2, lines 22-33; p. 3, lines 9-15), rats and mice (p. 3, lines 18-20); BALB/c mice (p. 1, lines 15-28), C57BL/6 mice (p. 1, line 36 to p. 2, line 6; Example 1; Figures 1-3), HuMab-mouse (p. 3, lines 23-30) and XenoMouse on a C57BL/6 background (p. 3, lines 23-30). The HuMab-mouse and XenoMouse are commercially available mouse strains transgenic for human immunoglobulin genes, and that the specification teaches may be used in the method of the invention (p. 3, lines 23-27).

Kucherlapati et al. (USPN 5,939,598; issue date August 17, 1999) teach inserting the human IgH_{hu} locus into a mouse genome (Col. 4, line 1-55; Col. 5, line 1 to Col. 8, line 24; Example 1) to obtain human monoclonal antibodies. Various transgenic hosts

are taught at Col. 3, lines 31-42, with mice being the preferred choice, and the C57BL/6 mouse strain as exemplary (as shown in the Example 1 at Col. 9, lines 29-32). Significantly, the transgenic mouse of Kucherlapati et al. is the same as the XenoMouse disclosed in the specification. This strain produces a diverse array of authentic fully human IgG kappa antibodies in the absence of mouse antibodies upon immunization with human antigens.

However, the specification does not teach or suggest how one skilled in the art could obtain a monoclonal antibody of human sequence and structure from a generic rodent germline genome. The method steps of combining a Th2 agonist with a Th1 antagonist are enabled for increasing production of antigen-specific monoclonal antibodies in mice where the antibody is mouse derived, and more especially, in the C57BL/6 strain. But, the specification does not further disclose those steps required to generate production of a human monoclonal antibody from just any rodent or any mouse antibody gene repertoire, or that in performing the instant claimed method steps, one would achieve this outcome.

The specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Thus Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make the claimed human monoclonal antibody from a rodent much less a C57BL/6 mouse in a manner reasonably correlated with the scope of the claims broadly including just any generic rodent or generic C57BL/6 mouse. The scope of the claims must bear a reasonable

correlation with the scope of enablement. See In re Fisher, 166 USPQ 19, 24 (CCPA 1970).

Without such guidance, the production of human monoclonal antibodies in a generic rodent or mouse strain is unlikely and undoubtedly unpredictable and the experimentation left to those skilled in the art is unnecessary and improperly extensive and undue. See Amgen, Inc v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 18 USPQ 1016 (Fed. Cir. 1991) at 18 USPQ 1026, 1027 and Ex Parte Forman, 230 USPQ 546 (BPAI 1986).

Due to the large quantity of experimentation necessary to demonstrate production of human monoclonal antibodies in generic rodents of C57BL/6 mouse strain, the lack of guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, the state of the art establishing transgenic mouse strains for human monoclonal antibody production, and the breadth of the claim which fails to recite the specific kind of rodent or mouse (e.g., whether transgenic for human immunoglobulin gene repertoire), the specification fails to teach the skilled artisan how to make and use the invention.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-15 are rejected under 35 U.S.C. § 103(a) as being obvious over Kucherlapati et al. (USPN 5,939,598; issue date August 17, 1999) in view of Cohen et al. (FASEB J. 12:1611-1626 (1998); cited in the IDS of October 16, 2003) and Ichikawa et al. (J.Immunol. 102:56-66 (2000); cited in the IDS of October 16, 2003) and further in view of Mikiyama et al. (USPN 5,264,209; issue date November 23, 1999; cited in the IDS of October 16, 2003) and Li et al. (Virology 269:54-65 (2000); cited in the IDS of May 19, 2004 under the PCT search report).

Claims 1-15 recite methods for generating monoclonal antibodies in rodents by co-administration of a Th2 agonist of pegylated IL-4 and Th1 antagonist of anti-IL-12 antibody, immunizing the rodents with a nucleic acid encoding an antigen by intradermal injection, and isolating the monoclonal antibodies. Claims 14 and 15 are more specifically directed to generating human monoclonal antibodies in C57BL/6 mice. Claim 14 is rejected for indefiniteness, *supra*, for step c) reciting the phrase "administering the antigen without a foreign adjuvant intradermally". For examination purposes, the Examiner refers to the specification at page 4, lines 24-26, where the phrase is interpreted to mean that the antigen is administered without any adjuvant.

It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced monoclonal antibodies against an antigen encoded by a nucleic acid by modulating the Th1 and Th2 response in a host as claimed in view of Kucherlapati et al., Cohen et al., Ichikawa et al., Mikiyama et

al. and Li et al.

Kucherlapati et al. teach the desirability of obtaining allogeneic antibodies especially in humans against human proteins, and the substantial interest in finding alternative routes to the production of allogeneic antibodies for humans (Col. 1, line 58 – Col. 2, line 6). The teaching of Kucherlapati et al. (see entire document) demonstrates homologous recombination methods for producing a mammalian host having at least one xenogeneic constant region capable of being spliced to a functional J region, or an entire immunoglobulin locus of the host substituted by a portion or an entire xenogeneic immunoglobulin locus, or a xenogeneic immunoglobulin locus inserted into a chromosome of the host cell and an inactivated endogenous immunoglobulin region. Kucherlapati et al. also teach inserting human IgH_{hu} locus into the mouse genome (Col. 4, line 1-55; Col. 5, line 1 to Col. 8, line 24; Example 1) to obtain monoclonal antibodies. Various transgenic hosts are taught at Col. 3, lines 31-42, with mice being the preferred choice, and the C57BL/6 mouse strain as exemplary (as shown in the Example 1 at Col. 9, lines 29-32). Kucherlapati et al. teaches immunizing the host with an immunogen and isolating the resultant antibodies by affinity columns having Fc binding properties (Col. 8, lines 33-39). Kucherlapati et al. teach the advantages of an antigenic or chimeric non-primate host, particularly a mouse host, for producing human monoclonal antibodies at Col. 13, lines 26-50.

Kucherlapati et al. do not teach administering pegylated IL-4 and an anti-IL-12 antibody or an intradermal injection of an antigen-encoding nucleic acid.

Cohen et al. teach cytokine modulation of the humoral immune response to a plasmid encoded protein antigen (see Table 4). With respect to IL-4, Cohen teaches: "Injection of a plasmid encoding IL-4 3 days before immunization with a protein antigen increased the antigen-specific antibody levels compared to protein immunization alone" (p. 1620, Col. 1, second paragraph); "Coinoculation of mice with plasmids encoding IL-4 and HCV core protein resulted in augmented antibody responses" (p. 1620, Col. 1, second paragraph); and "intranasal administration in liposomes of plasmids encoding HIV-1 env/rev and IL-4 resulted in higher antibody responses" (p. 1620, Col. 1, first paragraph continued to Col 2.). Cohen et al. also teach the suppressive effects of IL-12 on antibody production when the cytokine is administered with a plasmid encoding HIV-1/ env, gag/pol, nef and vif proteins (see Table 4 and p. 1621, Col. 1, second paragraph).

Mikayama et al. (Abstract; Col. 1-3) teach pegylation methods and pegylating high molecular weight serum polypeptides, preferably IL-6, in order to prolong the half-life and improve the pharmacokinetics and therapeutic efficacy.

Ichikawa et al. teach that anti-IL-12 Mab treatment of mice leads to enhanced production of IgG antibodies in a mouse model of multiple sclerosis when the mice are antigen challenged (Fig 4 and p. 64, Col. 2, second paragraph).

Finally, Li et al. teach that plasmids encoding an antigen can be administered intradermally to mice to elicit an antibody response (p. 56, Col. 1, second paragraph; Figure 1).

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the instant claimed methods for generating monoclonal antibodies in view of Kucherlapati et al., Cohen et al., Ichikawa et al., Mikiyama et al. and Li et al. The relative ability of IL-4 to enhance B cell antibody production and that of IL-12 to dampen or suppress B cell antibody production was recognized at the time of the invention, and based on the combined disclosures of Cohen and Ichikawa, there was sufficient motivation to modulate B cell production towards increasing the actual output through cytokine modifiers such as IL-4 and an anti-IL-12 antibody. Additionally, based on the combined disclosures of Cohen and Li, it was also known at the time of the invention, that a DNA-based antigen or a plasmid encoding an antigen, could be used to elicit an antibody response and that intradermal administration was successful. Increasing the serum half-life and biodelivery of a cytokine was also appreciated at the time of the invention, as Mikiyama teaches through pegylation methods and by example of the pegylated cytokine, IL-6. Accordingly, because the various recombinant technologies were available to modify a rodent as taught by Kucherlapati, and more specifically a mouse, to produce a greater output of not just any monoclonal antibody, but human monoclonal antibody, one skilled in the art would have been motivated and had an expectation of success in combining the reference disclosures to obtain the instant claimed methods for monoclonal antibody production.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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